

REMARKS

Claims 1-9, 11-15, 21, 27, and 32 are pending after entry of this paper. Claims 1-15, 20, 21, 27 and 32 have been rejected. Claims 10, 16-20, 22-26, 28-31 and 33 have been cancelled without prejudice. Applicants reserve the right to pursue cancelled claims in a divisional or continuing application.

Claims 1, 9, and 27 have been amended. Support may be found throughout the instant specification.

Claim 1 has been amended to replace “289 consecutive nucleotides” with “500 consecutive nucleotides” and to incorporate previously presented steps (d) and (e) into currently amended steps (c) and (d), respectively, for clarity. Additionally, claim 1 has been amended to replace the phrase “a complement” with “the complement.” No new matter is introduced with these amendments. Support can be found throughout the instant application, for example: on page 5, lines 6-9 of the specification as filed.

Claim 9 has been amended to replace “289 consecutive nucleotides” with “500 consecutive nucleotides” in step (a). Claim 9 has also been amended to incorporate the SEQ ID NOs. listed in previously presented step (b) into currently amended step (a) (i.e., SEQ ID NO. 6, SEQ ID NO. 8, or SEQ ID NO. 10). Additionally, step (b) has been amended to replace the phrase, “500 consecutive nucleotides of: SEQ ID NO. 6, SEQ ID NO. 8, or SEQ ID NO. 10; or” with “the complement of 500 consecutive nucleotides of SEQ ID NO. 2, SEQ ID NO. 4, SEQ ID NO. 6, SEQ ID NO. 8, or SEQ ID NO. 10” and step (c) has been deleted. No new matter is introduced with these amendments. Support can be found throughout the instant application, for example: on page 5, lines 6-9 of the specification as filed.

Claim 27 has been amended to replace “289 consecutive nucleotides” with “500 consecutive nucleotides.” No new matter is introduced with these amendments. Support can be found throughout the instant application, for example: on page 5, lines 6-9 of the specification as filed.

Response to Rejections under 35 U.S.C. §112, first paragraph (New Matter)

Claims 1-9, 11-15, 27, and 32 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner contends that recitation of “at least 289 consecutive nucleotides” is not supported in the specification and raises an issue of new matter (Office Action, page 4). Applicants respectfully disagree with the Examiner’s contention. However, in order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicants have amended independent claims 1, 9, and 27 to replace “289 consecutive nucleotides” with “500 consecutive nucleotides.” No new matter is introduced with this amendment and support can be found throughout the instant application, for example on page 5, lines 6-9 in the specification as filed. It should be noted that the Examiner has admitted that the “specification does provide support for the specific length limitation of 500 consecutive nucleotides on p. 5 lines 8-10” (Office Action, page 4).

Applicants assert that support for the amended claims is found within the specification as filed and, thus, the amended claims comply with the written description requirement. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph (new matter).

Response to Rejections under 35 U.S.C. §112, first paragraph (Written Description)

Claims 1-9, 11-15, 21, 27, and 32 stand rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. While the Examiner acknowledges that “nucleic acids consisting of SEQ ID NO. 2, 4, 6, 8, or 10 meet the written description requirements” (Office Action – Page 5), the Examiner contends that “‘a complement’ is being broadly interpreted as encompassing any fragment of SEQ ID NO. 2, 4, 6, 8, or 10 and not the full length sequences” and the “claims as written encompass fragments of at least 289 mer of SEQ ID No. 2, 4, 6, 8, 10, or 1, and any fragment of any length which is a complement...” (Office Action – Pages 5). Applicants respectfully disagree with the Examiner’s contention.

However, in order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicants have amended independent claims 1 and 9 to replace the phrase “a complement of” with “the complement of.” No new matter has been introduced with this amendment. Support can be found throughout the instant specification, for example on page 5, lines 6-9 of the application as filed. It should be noted that the Examiner has “suggested that the claims be amended to ‘the complement’ to encompass only the complement of the entire SEQ ID NO., or ... the complement of the [sic] at least 500 [consecutive nucleotides] of the SEQ ID NO.” (Office Action, page 8). Therefore, applicants assert that the amendment to the claims renders the Examiner’s contention moot, and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph (written description) to these claims.

The Examiner further contends that, “the claims as broadly written encompass isolated nucleic acids comprising fragments of SEQ ID NO. 1, 2, 4, 6, 8, or 10 without any description of the nucleotides flanking the fragments” (Office Action, page 5). Additionally, the Examiner states that “the claims as broadly written encompass the specification does not provide an adequate written description of the claimed genus of nucleic acids as the claims are broadly written” (Office Action, Page 5)... and “one skilled in the art would not recognize that applicant was in possession of the detection of ANY fragment of SEQ ID NO. 1, 2, 4, 6, 8, and 10” (Office Action, page 7). Applicants respectfully disagree with the Examiner’s contention.

As an initial matter, applicants believe that the amendment to the claims described in the proceeding paragraphs of this section (i.e., amending “a complement” to “the complement”) addresses the Examiner’s concerns with regard to these contentions. Furthermore, the applicants assert that the specification as filed provides adequate written description to demonstrate to a person of ordinary skill in the art that they were in possession of the invention at the time the application was filed.

The applicants respectfully direct the Examiner’s attention to Figure 2, which depicts the STS content of the 12q23-qter BAC RP11-0702C13 containing Gene 214. This figure diagrams the genomic sequence (i.e., SEQ ID NO:1). The Examiner has admitted that the “nucleic acids of SEQ ID NO. 2, 4, 6, 8, and 10 are alternatively spliced cDNAs from this sequence” (Office Action 11/20/06, page 3), which was the Examiner’s basis for the sequences to be rejoined. Hence, the applicants assert that the specification as filed provides a satisfactory disclosure regarding the genus/species.

The Examiner is also directed to the specification, which describes nucleotides which may flank the sequences of the instant invention:

Using the information provided in SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, and SEQ ID NO:10, one skilled in the art will be able to clone and sequence all representative nucleic acids of interest, including nucleic acids encoding complete protein-coding sequences. **It is to be understood that non-protein-coding sequences contained within SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, and SEQ ID NO:10 and the genomic sequence of SEQ ID NO:1 are also within the scope of the invention. Such sequences include, without limitation, sequences important for replication, recombination, transcription and translation.** Non-limiting examples include promoters and regulatory binding sites involved in regulation of gene expression, and 5'- and 3'- untranslated sequences (e.g., ribosome-binding sites) that form part of mRNA molecules. (Page 22, line 24 – page 23, line 8) (emphasis added).

Furthermore, there are a number of references throughout the instant specification which adequately describe sequences which can flank the SEQ ID NOs., for example:

The nucleic acids of this invention can be produced in large quantities by replication in a suitable host cell. **Natural or synthetic nucleic acid fragments, comprising at least 10 contiguous bases coding for a desired peptide or polypeptide can be incorporated into recombinant nucleic acid constructs, usually DNA constructs, capable of introduction into and replication in a prokaryotic or eukaryotic cell.** (page 70, lines 9-13) (emphasis added).

Nucleic acid constructs prepared for introduction into a prokaryotic or eukaryotic host will comprise a replication system recognized by the host, including the intended nucleic acid fragment encoding the selected protein or polypeptide, and will preferably also include transcription and translational initiation regulatory sequences operably linked to the protein encoding segment. Expression vectors may include, for example, an origin or replication or autonomously

replicating sequence (ARS) and expression control sequences, a promoter, an enhancer and necessary processing information sites, such as ribosome-binding sites, RNA splice sites, polyadenylation sites, transcriptional terminator sequences, and mRNA stabilizing sequences. Secretion signals are also included, where appropriate... **Such vectors may be prepared by means of standard recombinant techniques well known in the art...** (page 71, line 25 – page 72, line 14) (emphasis added).

Nucleic acids chosen, for example, from the nucleic acids set forth SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, or SEQ ID NO:1 for cloning the genes are prepared by polymerase change reaction (PCR). Synthetic oligonucleotide primers specific for the 5' and 3' ends of the nucleotide sequences are designed... **All forward primers (specific for the 5' end of the sequence) are designed to include an *NcoI* cloning site at the 5' terminus... All reverse primers (specific for the 3' end of the sequence) include an *EcoRI* site at the 5' terminus to permit cloning of the sequence into the reading from of the pET-28b.** The pET-28 vector provides a sequence encoding an additional 20 carboxyl-terminal amino acids including six histidine residues (at the C-terminus), which comprise the histidine affinity tag. (pages 75, line 26 – page 76, line 11) (emphasis added).

Moreover, the applicants assert that the specification provides adequate written description relating to the structure of several fragments of SEQ ID NOs. 1, 2, 4, 6, 8, and 10. For example, the Examiner's attention is respectfully directed to figures 10A and 10B, which depict the nucleic acid sequence of the exons of Gene 214 (which correspond to SEQ ID NOs. 38-45). It is noted that SEQ ID NO: 2 is comprised of SEQ ID NOs: 38, 40, and 39; SEQ ID NO: 4 is comprised of SEQ ID NO: 38 and 39; SEQ ID NO: 6 is comprised of SEQ ID NO: 38, 41, and 43; SEQ ID NO: 8 is comprised of SEQ ID NO: 38 and 42, and SEQ ID NO: 10 is

comprised of SEQ ID NO: 38 and 44. Thus, the Examiner's contention that, "one skilled in the art would not recognize that applicant was in possession of the detection of ANY fragment of SEQ ID NO. 1, 2, 4, 6, 8, and 10" (Office Action, page 7), is refuted by direct evidence and support in the specification, figures, and sequence listing, as filed.

Therefore, the applicants assert that the specification provides adequate written description of the nucleotide sequences of SEQ ID NOs. 1, 2, 4, 6, 8, and 10, in addition to fragments of these SEQ ID NOs. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph (written description).

Response to Rejections under 35 U.S.C. §102(a)

Claims 1, 2, 4-5, 8-9, 11-12, 15, and 27 are rejected under 35 U.S.C. 102(a) for allegedly being anticipated by GenBank Accession Number AI126846 (NCBI website October 26, 1998). Applicants respectfully disagree with the Examiner's contention.

However, in order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicants have amended independent 1, 9, and 27 to replace "289 consecutive nucleotides" with "500 consecutive nucleotides." No new matter is introduced with this amendment. Support can be found throughout the instant application, for example: on page 5, lines 6-9 of the specification as filed.

The Examiner's attention is respectfully directed to the MPEP guidelines which states, "'A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference'" (MPEP §2131). GenBank Accession Number AI126846 does not disclose a sequence which comprises "at least

500 consecutive nucleotides" of SEQ ID NO:1, 2, 4, 6, 8, or 10, as claimed in the instant invention. Therefore, applicants assert that the amended claims are not anticipated by GenBank Accession Number AI126846.

The applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a), in view of the above-mentioned amendments.

Response to Rejections under 35 U.S.C. §102(b)

Claims 1-5, 9, 11-12, and 32 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shankar, et al. (*Biochem. J.* 1994 Vol 300 p. 295) ("the Shankar reference") as evidenced by GenBank Accession Number U14383 (NCBI website December 31, 1994). Specifically, the Examiner contends that, "U14383 comprising at least 50 nucleotides which hybridize under stringent conditions to SEQ ID No. 2, 4, 6, 8, and 10... therefore GenBank Accession No. U14383 comprises 'a complement' of SEQ ID NO. 2,4,6,8, and 10. (Office Action, Page 12). Applicants respectfully disagree with this rejection.

However, in order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicants have amended independent 1, 9, to replace the phrase "a complement" with "the complement" as suggested by the Examiner (Office Action, page 13). No new matter is introduced with this amendment. Support can be found throughout the instant application, for example, on page 5, lines 6-9 of the specification as filed. The Examiner admits that "Shankar et al. does not teach a fragments [sic] comprising at least 289 consecutive nucleotides of [SEQ ID NO:]2 or [SEQ ID NO:]4" (Office Action, page

13). Therefore, applicants assert that the amended claims are not anticipated by GenBank Accession No. U14383 disclosed in the Shankar reference.

The applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a), based of the above-mentioned amendments.

Response to Rejections under 35 U.S.C. §103 (a)

Claims 6-7 and 13-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Shankar reference in view of Lasky, et al. (U.S. Patent No. 5,304,640 April 19, 1994) (“the Lasky reference”). Specifically, the Examiner contends that “it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have transformed human host cells with vectors comprising the nucleic acid taught by Shankar, et al” (Office Action, page 15). Applicants respectfully disagree with the Examiner’s rejection.

The applicants respectfully direct the Examiner’s attention to claims 6-7 and 13-14 which stand rejected. These claims depend from claim 1 and 9 which are directed to nucleic acids. The applicants assert that the sequences of claims 1 and 9 are non-obvious, since these claims have not been rejected on these grounds. Thus, the host cells containing vectors which contain the sequences of claims 1 and 9 are also non-obvious. Indeed, insertion of a non-obvious nucleic acid into a vector or host cell would not render that vector, host cell or nucleic acid obvious.

The applicants respectfully request reconsideration and withdrawal of rejections under 35 U.S.C. §103 (a) in view of the above mentioned claim amendments and remarks.

DEPENDENT CLAIMS

The applicants have not independently addressed all of the rejections of the dependent claims. The applicants submit that for at least similar reasons as to why independent claims 1, 9, 21, and 27 from which all of the dependent claims (2-8, 11-15, and 32) depend are believed allowable as discussed *supra*, the dependent claims are also allowable. The applicants however, reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 2976-4037US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 2976-4037US1.

Respectfully submitted,
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